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- (81) Designated States (national): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.**
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- Declaration under Rule 4.17:**
— of inventorship (Rule 4.17(iv)) for US only
- Published:**
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: **NOVEL PHARMACEUTICAL COMPOSITIONS FOR ANTIHISTAMINIC-DECONGESTANT COMBINATION AND METHOD OF MAKING SUCH COMPOSITIONS**

(57) Abstract: The present invention relates to pharmaceutical compositions of antihistamine-decongestant combination. Specifically the invention relates to bilayered tablet formulation comprising antihistaminic decongestant combination. More specifically present invention relates to the novel polymorph of fexofenadine or pharmaceutically accepted salts thereof, with at least one decongestant in the form of bilayered tablet. The preferred polymorphs are polymorph A and polymorph X of fexofenadine hydrochloride.



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INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 02/01068

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/20 A61K31/495 A61K31/445

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 267 986 B1 (JAIN GIRISH KUMAR ET AL) 31 July 2001 (2001-07-31) cited in the application column 2, line 44 - line 61 column 5 - column 10; examples ---	1, 9, 14, 16, 17
X	US 4 996 061 A (WEBB NORVAL E ET AL) 26 February 1991 (1991-02-26) cited in the application column 1, line 29 - line 48 column 3, line 52 - column 4, line 40 examples column 7, line 33 - line 41 claims --- -/-	1, 14, 16, 17

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
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- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

14 November 2002

Date of mailing of the international search report

25/11/2002

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 09957 A (HOECHST MARION ROUSSEL INC) 4 March 1999 (1999-03-04) page 3, line 14 - line 26 page 19; example 1 page 24; tables 2,3 page 30; tables 4,5 claims ---	1,5,14, 16,17
X	US 6 039 974 A (LEFLER JOHN R ET AL) 21 March 2000 (2000-03-21) column 2, line 52 -column 3, line 17 column 9, line 58 -column 10, line 17 column 15, line 12 - line 55 examples; tables column 16, line 30 -column 18, line 44 ---	1,5, 14-17
X	WO 01 85148 A (RANDALL DOUGLAS E ;AVENTIS PHARMA INC (US); NICHOLAS JAMES M (US)) 15 November 2001 (2001-11-15) page 1, line 10 - line 19 page 6 page 8, line 3 -page 10, line 20 claims 38-49 ---	1,5, 14-17
A	WO 01 94313 A (NOVARTIS ERFIND VERWALT GMBH ;NOVARTIS AG (CH); DAVIES JULIAN ANTH) 13 December 2001 (2001-12-13) page 1, line 1 - line 10 page 3 -page 5 page 7; example 1 figures ---	1-17
A	SIMPSON K ET AL: "FEXOFENADINE A REVIEW OF ITS USE IN THE MANAGEMENT OF SEASONAL ALLERGIC RHINITIS AND CHRONIC IDIOPATHIC URTICARIA" DRUGS, ADIS INTERNATIONAL LTD, AT, vol. 2, no. 59, February 2000 (2000-02), pages 301-321, XP001079065 ISSN: 0012-6667 page 310 -page 312 ---	1-17
A	SUSSMAN G L ET AL: "THE EFFICACY AND SAFETY OF FEXOFENADINE HCI AND PSEUDOEPHEDRINE, ALONE AND IN COMBINATION, IN SEASONAL ALLERGIC RHINITIS" JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, MOSBY - YEARLY BOOK, INC, US, vol. 104, no. 1, July 1999 (1999-07), pages 100-106, XP001055760 ISSN: 0091-6749 page 101 --- -/--	1-17

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 02/01068

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
T	<p>WO 02 080857 A (DOLITZKY BEN-ZION ;GROSS IRWIN (IL); TEVA PHARMA (IL); WIZEL SHLOM) 17 October 2002 (2002-10-17) page 3 -page 6 page 26 -page 37; examples -----</p>	1-17

INTERNATIONAL SEARCH REPORT

International application No.
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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 17
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claim 17 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box I.1

Claims Nos.: 17

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern: Application No

PCT/IB 02/01068

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